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APPLICATION NO. 09/218,688	FILING DATE 12/22/98	FIRST NAMED INVENTOR UNGER	ATTORNEY DOCKET NO. UNGER-1531
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EXAMINER SHARABER, S

ART UNIT 1516	PAPER NUMBER
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DATE MAILED:

10/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/218,660

Applicant(s)

Unger et al

Examiner

Shahnam Sharareh

Group Art Unit

1616



☒ Responsive to communication(s) filed on Dec 22, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-193 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-193 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-99, 116-121, 125-126 drawn to targeted compositions for imaging, a method of imaging and further a method of diagnosing the presence of a diseased tissue using said compositions classified in class 424, subclass 9.52.
 - II. Claims 100-103, 113-115, 122-124, 127 drawn to a therapeutic composition and the method of making, and the method of delivering said composition classified in class 424, subclass 450.
 - III. Claims 104-105, 108-111, drawn to a method of preparing a targeted composition, wherein the targeting ligand and the encapsulating vesicle are covalently bonded, classified in class 424, subclass 9.52.
 - IV. Claims 104, 106, drawn to a method of preparing a targeted composition wherein the targeting ligand and the encapsulating vesicle in unbounded form, classified in class 424, subclass 9.52.
 - V. Claims 104, 107, drawn to a method of preparing a targeted composition wherein the targeting ligand and the encapsulating vesicle are non-covalently bonded, classified in class 424, subclass 9.5.

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VI. Claims 128-169, drawn to compounds having the formula specified in the claim 128, classified in class 514, subclass 2.

VII. Claim 170-193, drawn to compounds having a hydrophobic moiety, a linking group and a targeting agent, classified in class 514, subclass 23+.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, V and VII, VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the invention I, II, III, IV, and V are drawn to targeted compositions and various methods of making and using said compositions, wherein said compositions are capable of existing and further being utilized in a manner unrelated to the specific compounds claimed in the inventions VII or VI.

3. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions may contain various hydrophilic, linking and targeting moieties that may comprise variety of chemical configurations, chemical bonds and dissimilar structural characteristics.

4. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the IV or V particulars of the subcombination as claimed for patentability, and (2) that the

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subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because targeted compositions comprising vesicles may be used as a contrast agent or gas delivery formulations which do not require to contain a bioactive moiety such as chemotherapeutic agents. The subcombination, on the other hand, has separate utility such as delivery of desired type of therapeutic drugs to a site or tissue of interest such as cancerous or ischemic tissues.

5. Inventions I or II and III, IV or V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process of bonding the targeting ligand to the lipid, protein or polymeric vesicle will create materially different products that may possess dissimilar properties such as rate of degradation secondary to the nature of the bonding employed.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. In addition, the search required for Group I, II, III, IV or V is not required for Group VI or VII, therefore, restriction for examination purposes as indicated is proper.

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Election of Species

7. This application contains claims directed to the following patentably distinct species of the claimed invention: various encapsulating precursors such as lipids, proteins or polymers (claims 1, 11-13, 16-17, 46-48, 51-54, 76-77), various phospholipids (claims 4-10, 39-45), various targeting ligands (claims 28-32, 59-63, 78-88), various functional groups (claims 128-193).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Also, it is considered that a Markush-type claim encompassing such species is directed to multiple independent and patentably distinct inventions since the species are so unrelated and diverse that a reference anticipating one of the species would not anticipate or render obvious the other species. Further, the species are considered to be independent since they are unrelated in

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operation, one does not require the other for ultimate use, and specification does not disclose a dependent relationship between them. Moreover, each of the stated species is considered to be patentably distinct from the others on the basis of its properties. Accordingly, a requirement to provisionally elect a single independent and patentably distinct species is made as provided for in MPEP § 803.02. It is noted that the claims encompass such final products as those set forth in Examples 1-62 disclosed on pages 131-181 of the Specifications.

In the event that the Markush-type claims are not found to be allowable, the examination of the claims presented will be limited to the Markush-type claims to the extent that they read on the elected species and claims directed solely to the elected species. The claims directed solely to the non-elected species will be held withdrawn from consideration.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. A telephone call was made to Mr. David Cherry on October 4, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

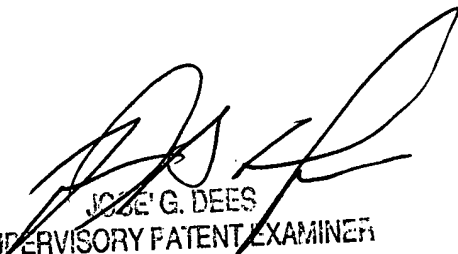
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnaz Sharareh, PharmD whose telephone number is (703) 306-5400.

sjs 10/04/99


JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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